

S/N Unknown

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: Jay Edelberg et al. Examiner: Patricia C. Mallari
Serial No.: Unknown Group Art Unit: Unknown
Filed: Herewith Docket: 1676.001US2
Title: ENHANCED BIOLOGICALLY BASED CHRONOTROPIC BIOSENSING

INFORMATION DISCLOSURE STATEMENT

Mail Stop Patent Application
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

In compliance with the duty imposed by 37 C.F.R. § 1.56, and in accordance with 37 C.F.R. §§ 1.97 *et. seq.*, the enclosed materials are brought to the attention of the Examiner for consideration in connection with the above-identified patent application. Applicants respectfully request that this Information Disclosure Statement be entered and the documents listed on the attached Form 1449 be considered by the Examiner and made of record. Pursuant to the provisions of MPEP 609, Applicants request that a copy of the 1449 form, initialed as being considered by the Examiner, be returned to the Applicants with the next official communication.

Pursuant to 37 C.F.R. §1.97(b), it is believed that no fee or statement is required with the Information Disclosure Statement. However, if an Office Action on the merits has been mailed, the Commissioner is hereby authorized to charge the required fees to Deposit Account No. 19-0743 in order to have this Information Disclosure Statement considered.

Pursuant to 37 C.F.R. §1.98(d), copies of the listed documents are not provided as these references were previously cited by or submitted to the U.S. Patent Office in connection with Applicants' prior U.S. application, Serial No. 09/848064, filed on May 03, 2001, which is relied upon for an earlier filing date under 35 U.S.C. §120.

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Page 2
Dkt: 1676.001US2

The Examiner is invited to contact the Applicants' Representative at the below-listed telephone number if there are any questions regarding this communication.

Respectfully submitted,

JAY EDELBURG ET AL.

By their Representatives,

SCHWEGMAN, LUNDBERG, WOESSNER & KLUTH, P.A.
P.O. Box 2938
Minneapolis, MN 55402
(516) 795-6820

Date Oct. 21, 2003 By



Robin A. Chadwick
Reg. No. 36,477

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**INFORMATION DISCLOSURE
STATEMENT BY APPLICANT**
 (Use as many sheets as necessary)

Complete if Known

Application Number	Unknown
Filing Date	Even Date Herewith
First Named Inventor	Edelberg, Jay
Group Art Unit	Unknown
Examiner Name	Mallari, Patricia

Attorney Docket No: 1676.001US2

Sheet 1 of 4

US PATENT DOCUMENTS

Examiner Initial *	USP Document Number	Publication Date	Name of Patentee or Applicant of cited Document	Class	Subclass	Filing Date If Appropriate
	US-5,187,096	02/16/1993	Giaever, I. , et al.	435	291	08/08/1991
	US-5,993,378	11/30/1999	Lemelson, J. H.	600	109	09/19/1994
	US-6,117,643	09/12/2000	Simpson, M. L., et al.	435	7.1	11/25/1997
	US-6,171,239	01/09/2001	Humphrey, D. R.	600	372	08/17/1998
	US-6,455,303	09/24/2002	Orwar, O. , et al.	435	287.1	12/02/1999

FOREIGN PATENT DOCUMENTS

Examiner Initials*	Foreign Document No	Publication Date	Name of Patentee or Applicant of cited Document	Class	Subclass	T ²

OTHER DOCUMENTS -- NON PATENT LITERATURE DOCUMENTS

Examiner Initials*	Cite No ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ²
		AIRD, W. , et al., "Vascular Bed-specific Expression of an Endothelial Cell Gene Is Programmed by the Tissue Microenvironment", <u>The Journal of Cell Biology</u> . 138(5), (1997),1117-1124	
		ANDERSON, J. L., et al., "A Software Sensor Using Neural Networks for Detection of Patient Workload", <u>Pace Vol. 21</u> , (1998 (Part II)),2204-2298	
		ANGLADE, F. , et al., "A study of the action of clonidine on secretion from the adrenal medulla in dogs", <u>Br. J. Pharmac.</u> 91, (1987),481-486	
		ANVERSA, P. , et al., "Morphometric Analysis of Coronary Capillaries during physiologic myocardial growth and induced cardiac hypertrophy", <u>A Review, Int. J. Microcirc: Clin Exp</u> 8, (1989),353-363	
		BOUSSE, LUC , "Whole cell biosensors", <u>Sensors and Actuators B</u> 34, (1996),270-275	
		BOUTE, W. , et al., "Introduction of an Automatic QT Interval Driven Rate Responsive Pacemaker", <u>Pace Vol. 11</u> , (1988 (Part II)),1804-1814	
		BRIGNOLE, M. , et al., "Pacing for Carotid Sinus Syndrome and Sick Sinus Syndrome", <u>Pace Vol. 13</u> , (1990 (Part II)),2071-2075	
		CELIKER, A. , et al., "Comparison of Normal Sinus Shythm and Pacing Rate in Children with Minute Ventilation Single Chamber Rate Adaptive Permanent Pacemakers", <u>Pace Vol. 21</u> , (1998 (Part I)),2100-2104	
		CHRISTINI, D. , "Direct biologically based biosensing of dynamic physiological function", <u>Am. J. Physiol. Heart Circ. Physiol.</u> , 280, (2001),pp. H2006-H2010	
		CHRISTINI, D. J., et al., "Practical Real-Time Computing System for Biomedical Experiment Interface", <u>Annals of Biomedical Engineering</u> , Vol. 27, (1999),180-186	
		CLEMENTY, J. , et al., "Clinical Significance of Multiple Sensor Options: Rate Response Optimization, Sensor Blending, and Trending", <u>The American Journal of Cardiology</u> , Vol. 83(5B), (1999),166D-171D	

EXAMINER**DATE CONSIDERED**

<p>Substitute for form 1449A/PTO</p> <p>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</p> <p>(Use as many sheets as necessary)</p>		<p>Complete if Known</p> <table border="1" style="width: 100%; border-collapse: collapse;"> <tr> <td style="width: 50%;">Application Number</td> <td style="width: 50%;">Unknown</td> </tr> <tr> <td>Filing Date</td> <td>Even Date Herewith</td> </tr> <tr> <td>First Named Inventor</td> <td>Edelberg, Jay</td> </tr> <tr> <td>Group Art Unit</td> <td>Unknown</td> </tr> <tr> <td>Examiner Name</td> <td>Mallari, Patricia</td> </tr> </table>		Application Number	Unknown	Filing Date	Even Date Herewith	First Named Inventor	Edelberg, Jay	Group Art Unit	Unknown	Examiner Name	Mallari, Patricia
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OTHER DOCUMENTS -- NON PATENT LITERATURE DOCUMENTS			T ²
Examiner Initials*	Cite No ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ²
		CLEMENTY, J. , et al., "Dual Chamber Rate Responsive Pacing System Driven by Contractility, Final Assessment After 1-Year Follow-up", <u>Pace Vol. 21</u> , (1998 (Part II)),2192-2197	
		CONNELLY, D. T., et al., "Initial Experience with a New Single Chamber, Dual Sensor Rate Responsive Pacemaker", <u>Pace, Vol. 16</u> , (1993),1833-1841	
		COOK, C. J., et al., "Real-Time Measurements of Corticosteroids in Conscious Animals Using an Antibody-Based Electrode", <u>Nature Biotechnology</u> , Vol. 15, (1997),467-471	
		CORNELL, B. A., et al., "A Biosensor that Uses Ion-Channel Switches", <u>Nature</u> , Vol. 387, (1997),580-583	
		DEN HEIJER, P. , et al., "Improved Rate Responsive Algorithm in QT Driven Pacemakers - Evaluation of Initial Response to Exercise", <u>Pace Vol. 12</u> , (1989),805-811	
		EDELBERG, J. M., et al., "Enhancement of Murine Cardiac Chronotropy by the Molecular Transfer of the Human B2 Adrenergic Receptor cDNA", <u>J. Clin. Invest.</u> , Vol. 101, No. 2, (1998),337-343	
		FRITZ, J. , et al., "Translating Biomolecular Recognition into Nanomechanics", <u>Science</u> , Vol. 288, (2000),316-318	
		FULMER, R. I., et al., "Transplantation of Cardioac Tissue into the Mouse Ear", <u>Department of Anatomy, Baylor University College of Medicine</u> , 273-281	
		GRECO, E. M., et al., "How to Program Rate Responsive Pacemakers", <u>Pace Vol. 23</u> , (2000),165-173	
		LAU, C. P., et al., "Pacemaker Mediated Tachycardias In Single Chamber Rate Responsive Pacing", <u>Pace Vol. 13</u> , (1990 (Part I)),1575-1579	
		LAU, C. P., et al., "Pacemaker Mediated Tachycardias In Single Chamber Rate Responsive Pacing", <u>Pace Vol. 13</u> , (1990 (Part I)),1575-1579	
		LEUNG, S. K., et al., "An Integrated Dual Sensor System Automatically Optimized by Target Rate Histogram", <u>Pace Vol. 21</u> , (1998),1559-1566	
		LEUNG, S. K., et al., "An Integrated Dual Sensor System Automatically Optimized by Target Rate Histogram", <u>Pace Vol. 21</u> , (1998),1559-1566	
		LUO, L. , et al., "Ion Channel Sensor", <u>Analytical Letters</u> 32(7), (1999),1271-1286	
		LUO, L. , et al., "Ion Channel Sensor", <u>Analytical Letters</u> 32(7), (1999),1271-1286	
		MAKINO, S. , et al., "Cardiomyocytes Can Be Generated From Marrow Stromal Cells In Vitro", <u>J. Clin. Invest.</u> 103(#5), (1999),697-705	
		MAKINO, S. , et al., "Cardiomyocytes Can Be Generated From Marrow Stromal Cells In Vitro", <u>J. clin. Invest.</u> , Vol. 103, No. 5, (1999),697-705	
		MALTSEV, V. A., et al., "Embryonic Stem Cells Differentiate In Vitro Into Cardiomyocytes Representing Sinusnodal, Atrial and Ventricular Cell Types", <u>Mechanisms of Development</u> 44, (1993),41-50	

EXAMINER

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		MALTSEV, V. A., et al., "Embryonic Stem Cells Differentiate In Vitro Into Cardiomyocytes Representing Sinusnodal, Atrial and Ventricular Cell Types", <u>Mechanisms of Development</u> 44, (1993),41-50	
		MARSHALL, A. , et al., "DNA Chips: An Array of Possibilities", <u>Nature Biotechnology</u> , Vol. 16, (1998),27-31	
		MOURA, P. J., et al., "Chronotropic Response of an Activity Detecting Pacemaker Compared with the Normal Sinus Node", <u>Pace Vol. 10</u> , (1987 (Part I)),78-86	
		MULCHANDANI, P. , et al., "Biosensor for Direct Determination of Organophosphate Nerve Agents 1. Potentiometric Enzyme Electrode", <u>Biosensors & Bioelectronics</u> 14, (1999),77-85	
		NAESSENS, M. , et al., "Whole-Cell Biosensor for Direct Determination of Solvent Vapours", <u>Biosensors & Bioelectronics</u> , Vol. 13, No. 3-4, (1998),341-346	
		OGAWA, H. , et al., "Heart Rate Responses to Autonomic Drugs in Sick Sinus Syndrome - Correlation with Syncope and Electrophysiologic Data", <u>Japanese Circulation Journal</u> , Vol. 55, (1991),15-23	
		OWICKI, J.C. , et al., "Biosensors Based on the Energy Metabolism of Living Cells: The Physical Chemistry and Cell Biology of Extracellular Acidification", <u>Biosensors & Bioelectronics</u> 7, (1992),255-272	
		PANCRAZIO, J. J., et al., "Development and Application of Cell-Based Biosensors", <u>Annals of Biomedical Engineering</u> , Vol. 27, (1999),697-711	
		RENDELL, M. S., et al., "The Relationship of Laser - Doppler Skin Blood Flow Measurements to the Cutaneous Microvascular Anatomy", <u>Microvascular Research</u> 55, (1998),3-13	
		RIVARD, A. , et al., "Age-Dependent Impairment of Angiogenesis", <u>Circulation</u> 99(1), (1999),111-120	
		RODRIGUEZ, R. D., et al., "Update on Sick Sinus Syndrome, a Cardiac Disorder of Aging", <u>Geriatrics</u> , Vol. 45, No. 1, (1990),26-36	
		ROWE-TAITT, C. A., et al., "Array Biosensor for Detection of Biohazards", <u>Biosensors & Bioelectronics</u> 14, (2000),785-794	
		STROBEL, J. S., et al., "Programming of Sensor Driven Pacemakers", <u>MD Consult - Journal Article</u> , Vol. 18, No. 1, (2000),1-22	
		SUGIURA, T. , et al., "A Self-Tuning Effect of Membership Functions in a Fuzzy-Logic-Based Cardiac Pacing System", <u>Journal of Medical Engineering & Technology</u> , Vol. 22, No. 3, (1998),137-143	
		SUTTON, R. , et al., "The Natural History of Sick Sinus syndrome", <u>Pace Vol. 9</u> , (1986 (Part II)),1110-11114	
		UPDIKE, S. J., et al., "A subcutaneous Glucose Sensor With Improved Longevity, Dynamic Range, and Stability of Calibration", <u>Diabetes Care</u> , Vol. 23, No. 2, (2000),208-214	
		WANG, T. L., et al., "Sick Sinus Syndrome as the Early Manifestation of Cardiac	

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		Hemochromatosis", <u>Journal of Electrocardiology</u> , Vol. 27, No. 1, (1994),91-96	
		WINDECKER, S. , et al., "Two-Year Experience with Rate-Modulated Pacing Controlled by Mixed Venous Oxygen Saturation", <u>Pace</u> Vol. 21, (1998),1396-1404	
		WONG, K. K., "Vascular Effects of Low and High Doses of Clonidine in Rats", <u>Artery</u> 20(4), (1993),180-188	

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Substitute Disclosure Statement Form (PTO-1449)

* EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. 1 Applicant's unique citation designation number (optional) 2 Applicant is to place a check mark here if English language Translation is attached